K070391

510(k) Summary - Elecsys PTH Test System

MAR 2 0 2007

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics
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Contact person: Kay A. Taylor

Date prepared: February 8, 2007

Device name

Proprietary name:	Elecsys PTH Immunoassay Elecsys PTH CalSet
Common name:	Parathyroid Hormone Assay Calibrator
Classification name:	Radioimmunoassay, Parathyroid Hormone Calibrator, Secondary

Device description

(1) The Elecsys PTH STAT Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

(2) The Elecsys PTH STAT CalSet is a lyophilized product consisting of human serum with added synthetic PTH in two concentration ranges. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

510(k) Summary - Elecsys PTH Test System, Continued

Intended use

(1) Immunoassay is for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.

(2) Used for calibrating the quantitative Elecsys PTH STAT assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers.

Substantial Equivalence

The Elecsys PTH STAT Test System (modified) is substantially equivalent to other devices legally marketed in the United States. The Elecsys PTH STAT Test System (modified) is equivalent to the Elecsys PTH System (K992680).

Device Comparison

The following table compares the Elecsys PTH STAT Test System (modified) and the predicate device. The predicate labeling used as the source document for the comparison is from that provided to FDA in K961481/A003.

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Reagent Intended Use/Indications for Use	Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.	Same
Calibrator Intended Use	Elecsys PTH CalSet is used for calibrating the quantitative Elecsys PTH assay for intact PTH (parathyroid hormone) on the Elecsys immunoassay analyzers	Elecsys PTH CalSet STAT is used for calibrating the quantitative Elecsys PTH STAT assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers
Platform(s)	Elecsys 1010, Elecsys 2010, MODULAR ANALYTICS E170, cobas e 411 and cobas e 601 analyzers.	Elecsys 1010, Elecsys 2010, cobas e 411 analyzers

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Assay Protocol	Sandwich assay	Same
Detection	Electrochemiluminescent	Same
Total Assay Duration	Elecsys 1010: **9 minute application** Elecsys 2010, cobas e 411 E170, and **cobas e** 601: **18 minute application**	9 minute application only
Sample Type	Human serum and plasma treated with K_3-EDTA.	Same
Calibrator	Elecsys PTH CalSet	Elecsys PTH STAT CalSet
CalSet Levels	Two	Same
Measuring Range	1.20 – 5,000 pg/mL	Same
Analytical sensitivity	1.20 pg/mL (0.127 pmol/L)	Same
CalSet Matrix	Human serum w/ synthetic PTH	Same
CalSet Storage	Lyophilized	Same
CalSet Target Conc.	Cal 1: ~0.05 pg/mL Cal 2: ~4500 pg/mL	Same
Traceability / Standardization	Standardized against a commercially available PTH test (RIA).	Standardized against Elecsys PTH (Cat. No. 11972103). This in turn was Standardized against a commercial PTH test (RIA).
Hook Effect	No high dose hook effect at PTH concentrations up to 17,000 pg/mL.	Same
Analytical Specificity	For the monoclonal antibodies used, the following cross-reactivities were found: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–Crosslaps: no cross-reactivity detectable.	Same – reworded to be more clear No cross-reactivities were found for: Osteocalcin, PTH fragment 1-37, bone-specific alkaline phosphatase, and β–CrossLaps.

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Reagent Stability	**Unopened:** 2-8°C – Up to the stated expiration date **Opened:** 2-8°C – 12 weeks On the E170/**cobas e** 601 and Elecsys 2010/**cobas e** 411: 8 weeks On the Elecsys 1010: 4 weeks (stored alternately in the refrigerator and on the analyzer- ambient temperature 20-25°C; up to 20 hours opened in total.)	Same **Opened:** 2-8°C – 12 weeks On Elecsys 2010/**cobas e** 411: 8 weeks On the Elecsys 1010: 4 weeks (stored alternately in the refrigerator and on the analyzer- ambient temperature 20-25°C; up to 20 hours opened in total.)
Calibration Interval	Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).	Same
Calibration Interval, continued	Renewed calibration is recommended as follows: E170/cobas e 601 and Elecsys 2010/cobas e 411: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).	Elecsys 2010/cobas e 411: After 1 month (28 days) when using the same reagent lot. After 7 days (when using the same reagent kit on the analyzer). Elecsys 1010: With every reagent kit. After 7 days (20-25°C). After 3 days (25-32°C).

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Precision	Elecsys 1010/ 2010: Within-run 5.4% CV @ 30.0 pg/mL 4.0% CV @ 62.2 pg/mL 4.0% CV @ 271 pg/mL 5.8% CV @ 44.3 pg/mL 3.4% CV @ 161 pg/mL 3.9% CV @ 702 pg/mL Total 5.9% CV @ 30.0 pg/mL 4.3% CV @ 62.2 pg/mL 4.3% CV @ 271 pg/mL 7.1% CV @ 44.3 pg/mL 5.0% CV @ 161 pg/mL 5.4% CV @ 702 pg/mL *E170:* Within-run 2.0% CV @ 25.0 pg/mL 1.2% CV @ 39.8 pg/mL 1.1% CV @ 139 pg/mL 2.2% CV @ 82.2 pg/mL 2.8% CV @ 265 pg/mL 0.6% CV @ 1,215 pg/mL Total 3.4% CV @ 26.4 pg/mL 2.5% CV @ 91.5 pg/mL 2.8% CV @ 269 pg/mL 1.7% CV @ 82.7 pg/mL 1.6% CV @ 267 pg/mL 1.6% CV @ 1,222 pg/mL	Elecsys 1010: Same Same Elecsys 2010/cobas e411 Within-run 2.1% CV @ 53.4 pg/mL 1.7% CV @ 215 pg/mL 1.7% CV @ 980 pg/mL 1.6% CV @ 52.6 pg/mL 2.0% CV @ 182 pg/mL 1.8% CV @ 744 pg/mL Total 3.8% CV @ 53.4 pg/mL 2.8% CV @ 215 pg/mL 2.5% CV @ 980 pg/mL 1.9% CV @ 52.6 pg/mL 2.5% CV @ 182 pg/mL 2.2% CV @ 744 pg/mL *E170:* Not applicable

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Limitations	The assay is unaffected by: **Icterus** (bilirubin <1,112 µmol/L or <65 mg/dL, **Hemolysis** (Hb < 0.932 mmol/L or < 1.5 g/dL), **Lipemia** (Intralipid < 1,500 mg/dL) **Biotin** (<205 nmol/L or < 50 ng/mL) • No interference was observed from rheumatoid factors up to a concentration of 1,500 IU/mL • In patients receiving therapy with high biotin doses (i.e > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration • In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found. As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been tested with monoclonal mouse antibodies or have received them for diagnostic purposes. In rare cases, interference due to extremely high titers of antibodies to ruthenium can occur.	Same except, Hemolysis (Hb < 0.155 mmol/L or < 0.25 g/dL; do not analyze samples that show visible signs of hemolysis)

Comparison Table

Feature	Predicate Device Elecsys PTH Assay	Modified Device Elecsys PTH STAT 9 minute application
Limitations, continued	• As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes. • In rare cases, interference due to extremely high titers of antibodies to ruthenium can occur. The test contains additives which minimize these effects. • Extremely high titers of antibodies to streptavidin can occur in isolated cases and cause interference. • For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical exam and other findings	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 2 0 2007

Re: k070391
Trade/Device Name: Elecsys Parathyroid Hormone Test System
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Codes: CEW, JIT
Dated: March 05, 2007
Received: March 06, 2007

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K070391

Device Name: **Elecsys PTH Test System**

Indications For Use:

Elecsys PTH Immunoassay (18 minute application)
Elecsys PTH STAT Immunoassay (9 minute application)
Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Elecsys PTH STAT CalSet
Elecsys PTH CalSet STAT is used for calibrating the quantitative Elecsys PTH STAT assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers.

Elecsys PTH CalSet
Elecsys PTH CalSet is used for calibrating the quantitative Elecsys PTH assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K070391